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11 UNITED STATES DISTRICT COURT
12 FOR THE EASTERN DISTRICT OF WASHINGTON
13

14 STATE OF WASHINGTON, *et al.*,

No. 1:23-cv-03026

15 Plaintiffs,

16 v.

DECLARATION OF NOAH T.
KATZEN

17 U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

18 Defendants.
19

20 Pursuant to 28 U.S.C. § 1746, I, Noah T. Katzen, hereby declare:

21 1. I am an attorney in the U.S. Department of Justice, Civil Division,
22 Consumer Protection Branch. I am assigned to represent Defendants in the above-
23 captioned case. The statements made herein are based on my personal knowledge,
24 and on information made available to me in the course of my duties and
25 responsibilities as Government counsel in this case.
26

2. I submit this declaration in support of Defendants' Cross-Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment

3. Filed herewith are true and correct copies of the following documents from the Administrative Record, cited in Defendants' Motion as "Defendants' Excerpts of Administrative Record (DEAR)":

Document Name	Bates Range	DEAR Page Range
Letter from CDER to Sandra P. Arnold, Population Council re: Approval (Sept. 28, 2000)	FDA 0003-5	1-3
Approved Labeling Text (Sept 28, 2000)	FDA 0006-17	4-15
Korlym Risk Assessment and Risk Mitigation Review	FDA 0292-306	16-30
Approval package index and approval letter for Supp. 20	FDA 0371-381	31-41
FDA Supplemental Approval letter (June 8, 2011)	FDA 1281-1284	42-45
Joint Motion and Order to Stay Case Pending Agency Review <i>Chelius v. Becerra</i> , 17-cv-0493 (D. Haw. May 7, 2021) ECF Nos. 148, 149	2021 REMS 000643-650	46-53
Letter from U.S. Food & Drug Admin. to Danco Laboratories, LLC re: REMS Modification Notification (December 16, 2021)	2021 REMS 001803-1807	54-58
Letter from U.S. Food & Drug Admin. to GenBioPro, Inc. re: REMS Modification	2021 REMS 001808-1811	59-62

Notification (December 16, 2021)		
NDA – supplemental application submission (June 22, 2022)	2023 SUPP 000257-350	63-156
ANDA – supplemental application submission (June 22, 2022)	2023 SUPP 00351-439	157-245
Joint Summary Review (January 3, 2023)	2023 SUPP 001112-1150	246-284
U.S. Food & Drug Admin. REMS Memo (December 16, 2021)	2021 REMS 001505-1508	285-288
U.S. Food & Drug Admin. Memorandum re adverse events from 10/1/21-12/3/22	2023 SUPP 001040-1051	289-300

I swear under penalty of perjury that the foregoing is true and correct.

Executed on December 11, 2024.

/s/ Noah T. Katzen
NOAH T. KATZEN